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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/698,046 | 10/30/2003 | Michael E. Landry | 5259-10801 | 1199 |
| 23492 | 7590 | 09/18/2006 | EXAMINER | |
| ROBERT DEBERARDINE ABBOTT LABORATORIES 100 ABBOTT PARK ROAD DEPT. 377/AP6A ABBOTT PARK, IL 60064-6008 | | | CUMBERLEDGE, JERRY L | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3733 | |

DATE MAILED: 09/18/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/698,046

Applicant(s)

LANDRY ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21,32-43,51,65,66 and 70 is/are pending in the application.
- 4a) Of the above claim(s) 13-20,65,66 and 70 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-12,21,32-43 and 51 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 October 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>02/03/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-12, 21, 32-43 and 51, drawn to a system for stabilizing the spine, classified in class 464, subclass 86.
- II. Claims 13-20, 65, 66 and 70, drawn to a method of stabilizing vertebrae, classified in class 606, subclass 61.

The inventions are distinct, each from the other because of the following reasons:

Inventions of Group I and Group II are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. The apparatus can be used to create a flexible joint in a patient.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Beth Vrioni on 09/06/06 a provisional election was made without traverse to prosecute the invention of a system for stabilizing a spine, claims 1-12, 21, 32-43 and 51. Affirmation of this election must be made by

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applicant in replying to this Office action. Claims 13-20, 65, 66 and 70 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-7 recite the limitation "the coupling mechanism", all in line 1 of the respective claim. There is insufficient antecedent basis for this limitation in the claim. The coupling mechanism is not positively recited in the prior claim (claim 1), but is only functionally recited.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 21 is rejected under 35 U.S.C. 102(e) as being anticipated by Roger (US Pat. 6,592,587 B1).

Roger discloses a flexible (column 6, lines 15-16) member (Fig. 4, ref. 20) for a spinal stabilization system, comprising: a first section comprising a first stiffness (column 6, lines 15-16); a second section comprising a second stiffness (column 6, lines 15-16); and wherein the stiffness of the second section is greater than the stiffness of the first section. Since the flexible member can be made of two different materials (a polymeric material and another material), the wire will have at least two sections- a first section made of one material and a second section made of another material. Since the two different sections are made of two different materials that have different physical properties, the two sections will exhibit different stiffness. The section with the material that is stiffer can be considered the second section, and the section with the material that is less stiff can be considered the first section.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-12, 21, 32-43 and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Benzel et al (US Pat. 5,713,900) in view of Roger (US Pat. 6,592,587 B1).

Benzel discloses a system for stabilizing a spine, comprising: a first threaded member (Fig. 1, ref. 92, top left screw) configured to couple to a first bone during use; a second threaded member (Fig. 1, ref. 92, bottom left screw) configured to couple to a second bone during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14), wherein the coupling mechanism is configured to couple the first threaded member to the second threaded member during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14), wherein the coupling mechanism is positionable using the first flexible member and the second flexible member during use, and wherein the coupling mechanism is configured to couple the first threaded member to the second threaded member during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14), wherein the coupling mechanism comprises: a first ring (Fig. 4, ref. 78) configured to engage a portion of the first threaded member during use; and a second ring (Fig. 4, ref. 78) configured to

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engage a portion of the second threaded member during use. The system further comprises a coupling mechanism, wherein the coupling mechanism comprises a ring (Fig. 4, ref. 78) configured to engage a portion of the first threaded member or the second threaded member during use. The system further comprises a coupling mechanism, wherein the coupling mechanism comprises: a first ring (Fig. 4, ref. 78) comprising protrusions (Fig. 4, ref. 84) (column 3, lines 49-52) configured to engage protrusions on a head of the first threaded member (Fig. 3, ref 42) during use; and a second ring (Fig. 4, ref. 78) comprising protrusions (Fig. 4, ref. 84) (column 3, lines 49-52) configured to engage protrusions on a head of the second threaded member during use. The system further comprises a coupling mechanism, wherein the coupling mechanism comprises: a first connector (Fig. 1, ref. 14) configured to engage the first threaded member positioned in bone; a second connector (Fig. 1, ref. 12) configured to engage the second threaded member positioned in bone; and an elongated section (Fig. 1, ref. 10) configured to couple the first connector to the second connector.

Benzel further discloses a system for stabilizing a spine comprising: a first threaded member (Fig. 1, ref. 92, top left screw) configured to couple to a first vertebra during use; a second threaded member (Fig. 1, ref. 92, bottom left screw) configured to couple to a second vertebra during use; and a coupling mechanism (Fig. 1 ref. 10, 12 and 14) comprising: a first connector (Fig. 1, ref. 14) configured to engage a portion of the first threaded member during use; a second connector (Fig. 1, ref. 12) configured to engage a portion of the second threaded member during use; and an elongated member (Fig. 1, ref. 10) configured to couple to the first connector and the second

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connector such that the first vertebra is coupled to the second vertebra; and wherein at least one of the threaded members comprises an inner conduit (Fig. 3, ref. 52) configured to couple to a flexible member during use. At least one of the connectors comprises a curvate wall (Fig. 3, near ref. 38) to engage a portion of a ring during use. The first threaded member comprises a threading (Fig. 3, ref. 52), and wherein the threading is configured to engage threading of a flexible member. The system further comprises a ring (Fig. 4, ref. 78) configured to couple at least one of the threaded members to at least one of the connectors during use; and wherein at least one of the connectors is configured to frictionally lock the ring. When the screw is fully engaged into the bone, the screw head will frictionally hold the ring in place.

Benzel further discloses a system for stabilizing a spine, comprising: a first threaded member (Fig. 1, ref. 92, top left screw) configured to couple to a first portion of bone during use; a second threaded member (Fig. 1, ref. 92, bottom left screw) configured to couple to a second portion of bone during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14) configured to couple the first threaded member to the second threaded member during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14) positionable using the first flexible member and the second flexible member during use, and wherein the coupling mechanism is configured to couple the first threaded member to the second threaded member during use. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14) comprising: a first ring (Fig. 4, ref. 78) configured to engage a portion of the first threaded member during use; and a second ring (Fig. 4, ref. 78) configured to

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engage a portion of the second threaded member during use. The system further comprises a coupling mechanism comprising: a first connector (Fig. 1, ref. 14) configured to engage the first threaded member positioned in bone; a second connector (Fig. 1, ref. 12) configured to engage the second threaded member positioned in bone; and an elongated section (Fig. 1, ref. 10) configured to couple the first connecting section to the second connecting section. The system further comprises a coupling mechanism (Fig. 1 ref. 10, 12 and 14) comprising at least one connector (Fig. 1, ref. 14) configured to engage a threaded member during use. The first flexible member is positionable through the first threaded member opening in a coupling mechanism during use. The first flexible member is positionable through the first threaded member opening in a coupling mechanism during use, and wherein the second flexible member is positionable through a second threaded member opening in the coupling mechanism during use.

Benzel further discloses a bone stabilization system, comprising: a threaded member (Fig. 1, ref. 92, top left screw) comprising one or more protrusions (Fig. 3, ref. 42) on a head of the threaded member; a ring (Fig. 4, ref. 78) configured to engage protrusions on the head of the threaded member during use; a coupling mechanism (Fig. 1 ref. 10, 12 and 14) configured to engage the threaded member during use comprising: an opening (Fig. 4, ref. 79) through a connector configured to engage the threaded member during use; and a locking mechanism (Fig. 3, ref. 60, the insert) configured to couple the threaded member to the ring during use; and wherein the system is configured such that interaction of protrusions on the head of the threaded

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member and the ring inhibits rotation of the threaded member in the bone during use.

Benzel further discloses a ring (Fig. 4, ref. 78) configured to couple a threaded member to a coupling mechanism during use, comprising: a first surface configured to engage a wall of the coupling mechanism during use (the surface between the end of the ring and the beginning of the coupling mechanism); a second surface configured to engage a locking mechanism during use (sloped surface adjacent the surface of ref. 140); and a third surface comprising one or more teeth (surfaces near ref. 138) configured to engage a portion of the threaded member during use such that rotational movement of the threaded member in bone during use is inhibited.

Benzel does not disclose a first flexible member; a second flexible member; the first flexible member and the second flexible member are guides; one or more guiding mechanisms; a first flexible member; and a second flexible member; at least one of the flexible members comprising a cable; at least one of the flexible members comprising a variable thickness cable; at least one of the flexible members comprises a stopping mechanism.

Roger discloses a first flexible member (Fig.3b, ref. 21); a second flexible member (Fig. 3a, ref. 21); the first flexible member and the second flexible member are guides (column 5, lines 37-40); one or more guiding mechanisms (Fig.3b, ref. 21); a first flexible member (Fig.3b, ref. 21); and a second flexible member (Fig. 3a, ref. 21); at least one of the flexible members comprises a cable (column 5, lines 44-45); and at least one of the flexible members comprises a variable thickness cable (Fig. 3b, ref. 21). Since the cable can be threaded, there will be a varying thickness along the cable. The

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cable will be thicker where there is threading and narrower where there is no threading.

At least one of the flexible members comprises a stopping mechanism (Fig. 4, ref. 10).

The flexible members (or guides) are used for guiding a securing member in the appropriate direction to achieve fixation of the objects to be fastened in a desired alignment (column 5, lines 37-40).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have used the flexible members (or guides) of Roger with the threaded member of Benzel, in order to guide a securing member in the appropriate direction to achieve fixation of the objects to be fastened in a desired alignment (column 5, lines 37-40).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER